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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/284,421 06/11/99 GORDON

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IM62/0109

EXAMINER

BEX, P

ART UNIT

PAPER NUMBER

1743

DATE MAILED:

01/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/284,421

Applicant(s)

GORDON, JOHN FRANCIS

Examiner

P. K. Bex

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☒ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 17) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: _____.

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DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "80" has been used to designate both printer and microscope in Fig. 5. Correction is required.
2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the disc which is molded in one piece with a plurality of wells must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. *claim 8*

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: there is no disclosure within the specification of a disc that is molded from one piece with a plurality of wells, as disclosed in claim 8.
1. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.

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- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
 - 1. Field of the Invention.
 - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

Claim Objections

4. Claim 33 is objected to because of the following informalities: A claim which depends from a dependent claim should not be separated by any claim which does not also depend from said dependent claim. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2-7 and 10-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. Examples of some unclear and indefinite terms used in the claims are:

Claim 2, line 2, the phrase "shallow enough" is a relative phrase which renders the claim indefinite. The phrase "shallow enough" is not defined by the claim, the specification does not

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provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. How “shallow” is enough?

Claim 3, line 2, the phrase “deep enough” is a relative phrase which renders the claim indefinite. How “deep” is enough?

Line 3, “in the space” lacks antecedent basis.

Claim 4, line 2, “sector-shaped” is indefinite. What shape is “sector-shaped”? Same deficiency was found in claims 5-7, 9, 11 and 27.

Line 3-4, it is not clear as to how a “handle” functions to facilitate locating the sector on a disc.

Claim 6, line 3, the conditional term “can” is not a positive recitation, therefore, renders the claim indefinite.

Claim 10, line 2, “the disk structure” lacks antecedent basis.

Line 3, “its” is vague and indefinite as to what element it refers to.

Claim 11, line 2, recites the limitation “sector inserts”. There is insufficient antecedent basis for this limitation in the claim.

Claim 12, line 2, the phrase “closely spaced” is a relative phrase which renders the claim indefinite. How “close” is close?

Claim 13, line 3, the phrase “small” is a relative phrase which renders the claim indefinite. How “small” is sufficient? Same deficiency was found in claim 19.

Line 4, it is not clear as to what applicant means by “capillary-like action”. How is this different than capillary action, i.e. wicking, gravity or diffusion flow?

Claim 16, line 2, recites the limitation “the surfaces”. There is insufficient antecedent basis for this limitation in the claim. What surfaces is applicant referring to?

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Claim 19, line 3, the phrase “similar liquid injecting device” is indefinite. It is not clear as to what applicant means by “similar”.

Claim 26, line 5, “both directions” lacks antecedent basis. Which directions is applicant referring to? No reference axis is provided.

Claim 29, line 2, “the vent opening” lacks antecedent basis.

Claim 32, line 2, the phrase “of the above first aspect” unclear and indefinite as to what applicant is referring to. Same deficiency was found in claim 38. This recitation in the preamble does not conform with U.S. patent practice. The limitations “said chamber” in line 4, “said openings” in line 5 and “the other opening” in line 7 all lack proper antecedent basis. Further, it is not clear from the claim as what is meant by “withdrawing fluid from the chamber through the same or other opening to leave liquid in the wells”. In the process of withdrawing the liquid it does not make sense to leave liquid in the wells.

Claim 33, line 3, “the fluid inlet” lacks antecedent basis.

Claim 34, line 5, the phrase “sufficient to allow” is indefinite. It is not clear at what spaced locations are “sufficient” to allow monitoring of the wells.

Claim 36, line 2, “the first fluid” lacks antecedent basis.

Claim 37, line 3, “the automated fluid handling apparatus” lacks antecedent basis.

Applicant is required to review and correct these errors so that the claims conform to U.S. patent practice.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 1-3, 12-13, 17-18, 20, 32, 34-36 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Inoue *et al* (USP 5,955,352).

Inoue *et al* teach a multi-well assay disc plate comprising; a first upper surface 1, a second lower surface 21 having a plurality of wells 3 disposed therein, the first and second surfaces defining a chamber having an inlet and outlet which allows fluids to be introduced and withdrawn from the chamber, the wells being proportioned and dimensioned to retain a volume of fluid in each well following withdrawal of the liquid (column 2, lines 3-9, column 13, line 15- column 16, line 50, Figs. 11-17).

8. Claims 1-3, 8, 11-13, 17, 21-22, 25, 32 and 34-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Croteau *et al* (USP 5,700,655).

Croteau *et al* teach a multi-well assay disc plate 10 comprising; a first upper surface 14, a second lower surface having a plurality of wells 12 disposed therein, the first and second surfaces defining a chamber having an inlet 22 and outlet 24 which allows fluids to be introduced and withdrawn from the chamber, the wells being proportioned and dimensioned to retain a volume of fluid in each well following withdrawal of the liquid (column 4, line 52- column 6, line 60, Fig. 2A-4B).

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 4-11, 14-16, 19, 21-31, 33, 37 and 39-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue *et al* (USP 5,955,352) in view of Merkh *et al* (USP 5,281,540).

Inoue *et al* as discussed previously, do not teach a plate structure which is divided into sectors with a handle at the longer arc-portion to facilitate locating the sector on a disc. However, such a handle is considered conventional in the art, see Merkh *et al*. Merkh *et al* do teach a plate structure which is divided into sector inserts 80 comprising wells 84 and a handle at the longer arc-portion with a information panel 96 which functions to facilitate locating the sector insert on a disc 18(Figs. 1-2, 4-5). Such a handle allows the operator to access patient information corresponding to the particular assay sector insert (column 10, line 60- column 11, line 21). Note that Merkh *et al* also teach sectors inserts and a disc which include lock 100, 102, 104 and key 93 portions to allow the sectors to be snap-fitted in the correct orientation and the disc comprising plurality of dividing walls 122.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the assay apparatus of Inoue *et al* the handle means, as taught by Merkh *et al*, in order allow the operator to access patient information corresponding to the particular assay sector.

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Conclusion

10. No claims allowed.

11. The prior art made of record and not relied upon which is considered pertinent to applicant's disclosure are Schellenberger *et al*, Oldenburg *et al*, Bohannon *et al*, Semthers *et al*, Long, Fox, Anderson *et al*, Barker *et al* and Noack. They are cited of interest in that they show various test arrays for performing assays.


12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697.

The fax number for the organization where this application or proceeding is assigned is (703) 305-7718 for official papers prior to mailing of a Final Office Action. For official papers after mailing of a Final Office Action, use fax number (703) 305-3599. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.



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01/03/01



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